

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S. Appln. No. 09/445,963

REMARKS

Review and reconsideration on the merits are requested.

Claims 1-4 are rewritten; rough correspondence to new claims is as follows:

Claim 1 is approximated in claim 5.

Claim 2 is approximated in claim 6.

Claims 3 and 4 are approximated in claim 7.

Method claims 8-11 are added approximating claims 1/3 (claims 8 and 9) and claims 2/4 (claims 10 and 11).

Applicants assume the art rejections would apply against the new claims which correspond to original claims 1 to 4.

Applicants first address the art rejections. All references are identified in PTO-892 (Rev. 03-98). The references are referred to herein as Kajiwara (Ref. N), Jichlinski (Ref. U), Kennedy (Ref. V) and Jaffe (Ref. W).

Claims 1/5 and 2/6 are rejected as anticipated by Jichlinski.

Claim 2/6 is rejected as anticipated by Kennedy.

Claims 3/7 and 4/7 are rejected as anticipated by Kajiwara.

Claim 1/5 is rejected as unpatentable over Jichlinski in view of Jaffe.

These rejections are respectfully traversed.

The Examiner's position on the prior art is set forth in the Action and will not be repeated here except as necessary. The "base" compound 5-aminolevulinic acid is referred to herein as ALA.

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Jichlinski and Kennedy

These two references only disclose the possibility of photokinetic diagnosis or treatment using ALA. They do not disclose the isotope of the present invention.

Applicants thus submit that the anticipation rejections set forth in Paragraphs 6 and 7 of the Action are improper and request withdrawal.

Kajiwara

Kajiwara only discloses that ^{13}C -ALA is useful for the study of biosyntheses, metabolism or “diagnosis” as a general concept. In Kajiwara, a specific labeled compound is metabolized, and the resulting compound is separated and purified, followed by NMR measurement to thereby estimate the degree of metabolism based on structural analysis. Kajiwara does not specifically disclose that ^{13}C -ALA is used for detection or diagnosis in the sense of the present invention.

Separation and purification are not carried out in the diagnosis (detection) of the present invention.

Applicants request withdrawal of the anticipation rejection of claims 3/7 and 4/7.

Obviousness Rejection over Jichlinski in view of Jaffe

The present invention and Jichlinski both involve the fact that ALA accumulates to a malignant tumor.

However, neither Jichlinski nor Jaffe disclose or suggest that a malignant tumor can be detected or diagnosed using MRI or the like by substituting the claimed isotope for ALA. Accordingly, the present invention is not suggested by the combination of Jichlinski and Jaffe.

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In the field of structural analyses and metabolic studies, conventional compounds are structurally analyzed with NMR by introducing a stable isotope into the compounds as a general technique (e.g., Kajiwara, Jaffe).

However, in such techniques, the reactant must be separated and purified and the compound to be examined must be subjected to NMR spectral measurement. Even if techniques from the field of structural analysis and metabolic studies are combined with Jichlinski (disclosing that porphyrins accumulate to a tumor in the administration of ALA), one of ordinary skill in the art would not find obvious application to detection or diagnosis in the sense of the present invention.

The present invention and Jichlinski both relate to the treatment of a malignant tumor. However, in the present invention, the position of the malignant tumor can be more easily identified using MRI or the like as compared to Jichlinski. Therefore, more effective treatment can be expected by combination with laser treatment or the like in the present invention as compared to the prior art relied on.

Withdrawal is requested.

Having addressed the art rejections, Applicants now turn to the claim rejections under 35 U.S.C. § 112.

Turning first to the second paragraph rejection, Applicants change the "agent" claims to compound as an ALA isotope claims. The compound can be in the form of the ester, etc., of the isotope.

Applicants believe that the claims are now clear, and request withdrawal.

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With respect to the difference between a diagnostically and pharmaceutically acceptable carrier, these two terms, in Applicants' view, have the same meaning and they are used interchangeably in the claims. If the Examiner wishes only one term to be used, the Examiner is requested to telephone the undersigned.

With respect to the claims not being drawn to a method of use, claims to a method of use are added. If the Examiner finds these incompatible with claims not directed to a method of use, Applicants offer to cancel all claims but the method of use claims and pursue only method of use claims.

Turning now to the first paragraph rejection, the claims are limited to detecting which it is believed responds to the rejection of the Examiner.

The specification makes it quite clear that the accumulation of the labeled ALA is indicative of only malignant tumors.

Withdrawal of all rejections under 35 U.S.C. § 112 is requested.

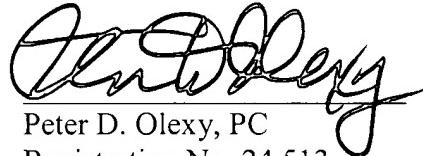
Turning now to Specification, the points noted by the Examiner have been corrected.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,



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APPENDIX
VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

The specification is changed as follows:

Page 1, following the title, please insert:

--This is a 371 of Application No. PCT/JP98/02648 filed June 16, 1988.--

Page 28, line 1, delete “CLAIMS” and insert therefor --WE CLAIM--.

IN THE CLAIMS:

Claims 1-4 are canceled.

Claims 5-11 are added as new claims.